Docket No.: SOHN-P01-001 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Warren Stern

Confirmation No.: 8880

Application No.: 10/687,470

Art Unit: 1616

Filed: October 16, 2003

For: METHOD OF TREATING SNORING AND OTHER OBSTRUCTIVE BREATHING DISORDERS

Examiner: SCHLIENTZ, N. W.

DECLARATION OF WARREN STERN UNDER 37 C.F.R. § 1.131

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Warren Stern, Ph.D., of 322R Center Hill Road, Plymouth, MA 02360 state that I am the sole inventor of the above-identified patent application disclosing the subject matter presently claimed in the pending claims.

1. I am Executive Vice President of Drug Development for QRxPharma of Bedminster, NJ. I have been conducting research in the field of clinical drug development for approximately 30 years. A copy of my resume is enclosed herein.

2. I understand that the Examiner has rejected certain claims of the pending application as being not novel in view of the published Barth *et al.* PCT Application WO 03/097011 A1 (herein the "Barth PCT Application"), having an effective international filing date of May 16, 2003, and claiming the benefit of the filing dates of three U.S. Provisonal Application Nos. 60/380,855, filed on May 17, 2002; 60/404,154, filed on August 19, 2002; and

60/449,838, filed on February 27, 2003. I have carefully reviewed the disclosure of the Barth PCT Application and its three priority U.S. Provisional Applications. I did not find in U.S. Provisonal Application No. 60/380,855, filed on May 17, 2002, any disclosure relating to snoring or sleep apnea.

3. The pending claims of the above-referenced application are directed to methods of reducing partial nocturnal upper airway obstruction or primary snoring in a patient in need thereof, comprising administering to the patient an agent for treating symptoms of hyper-acidity or gastro-intestinal reflux disease (GERD). A U.S. Provisional Application describing the invention was filed as U.S.S.N. 60/419,072, on October 16, 2002, to which the above-referenced U.S. utility application claims the benefit of its filing date.

4. Example 1 of the above-referenced application, describing the effectiveness of PREVACID™ (Lansoprazole), ZANTAC™ (ranitidine), TAGAMET™ (Cimetidine) and PEPCID™ AC (Famotidine) in reducing snoring symptoms in a single patient, was first disclosed in U.S. Provisional Application 60/419,072, filed on October 16, 2002. Example 2 of the above-referenced application, describing an open label study to assess the effectiveness of PREVACID™ (Lansoprazole), performed on 8 outpatients with significant snoring, was first disclosed in the above-referenced application.

5. As evidenced, *inter alia*, by **Exhibits A - C** attached hereto, I conceived and successfully reduced to practice at least one embodiment of the claimed invention before May 17, 2002, the earliest possible effective filing date of the Barth PCT Application.

6. **Exhibit A** is a copy of an Agreement entered between I (Warren Stern) and SohnStearns, LLC, on a date (redacted) before May 17, 2002. The Agreement relates to the formation of a new company "Newco," for the purpose of developing intellectual property, obtaining patents, and commercializing a pharmaceutical for the treatment of snoring, sleep apnea and related disorders (see paragraphs 1 and 2 of the Agreement). Under the Agreement, my contribution to the Newco is to provide Newco with intellectual property related to snoring (paragraph 4 of the Agreement), and to contribute to Newco a protocol for performing clinical trials for the snoring related pharmaceutical (paragraph 7 of the Agreement). **This**

shows that I was in possession of the invention and a clinical trial protocol as of the date of the Agreement, which is prior to May 17, 2002.

7. **Exhibit B** is a Confidentiality Agreement entered between Doug Bell, M.D., then a clinical instructor at Harvard Medical School, and Steve Sohn, M.D., a member of SohnStearns, LLC, on a dated (redacted) before May 17, 2002. Pursuant to the Confidentiality Agreement, Dr. Bell will receive information related my invention "concerning a new pharmaceutical treatment of snoring, insomnia and related sleep disorders," for the purpose of conducting clinical trials in a group of snoring patients in order to further verify my invention. **This also shows that I was in possession of the invention and a clinical trial protocol as of the date of the Confidentiality Agreement, which is prior to May 17, 2002.**

8. **Exhibit C** is one of eight Data Extraction Forms used in the study conducted under the Confidentiality Agreement shown in **Exhibit B**, and subsequently described in Example 2 of the above-referenced application. The Data Extraction Form indicates that the start date for this patient was prior to May 17, 2002, and the end date for this patient was prior to August 19, 2002 (the filing date of the Barth U.S. Provisional Application 60/404,154). **This further shows that I was in possession of the invention prior to May 17, 2002, or at least prior to August 19, 2002.**

9. The undersigned hereby declare that all statements made herein are of their own knowledge and are true, and all statements made on information and beliefs are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Warren Stern
Warren Stern

June 5, 2008
Date

WARREN C. STERN, Ph.D.
Executive Vice President,
Drug Development
QRxPharma, Inc.
1400 US Highway 206N
Bedminster, NJ 07921
warren.stern@qrxpharma.com
908-506-2900
617-688-1345 (cell)

EDUCATION

- Indiana University, Ph.D., Psychopharmacology, 1969
- City University of New York (Brooklyn College), B.S.,1965

SUMMARY OF EXPERIENCE

More than 25 years of pharmaceutical product development experience in a wide variety of therapeutic areas and drug delivery systems, including preclinical (pharmacology, ADME, formulation development, toxicology) and clinical research in early stage companies, pharma and CROs, first in man clinical trials, coordination of complex multicenter phase II-III clinical studies and IND/NDA/sNDA submissions. Areas of expertise include preclinical and clinical testing of psychiatric and neurological disorders, asthma, obesity, bone metabolism, pain, stroke, diabetes and other therapeutic areas, oral and parenteral drug delivery systems, regulatory considerations, intellectual property strategy, commercial relationships with pharmaceutical companies and government agencies. Holds 10 pharmaceutical use-patents and has several patent applications pending.

Entrepreneurial experience includes CEO/President position at a publicly held early stage drug delivery company (Pharmatec), co-founding of Research Triangle Pharmaceuticals (a subsidiary of Cato Holdings; acquired by SkyePharma) and founding of Nobex Corp. (acquired by Biocon).

EXPERIENCE

Executive Vice President, Drug Development, QRxPharma, Inc., Bridgewater, NJ 2007-present (90% time)

QRx is focused on development of novel formulations of analgesics. Using a virtual model of CROs/consultants, lead the phase II/III program. Lead regulatory strategy, clinical trial design/execution; participate in corporate management of company (IPO completed in May, 2007).

Senior Vice President, Drug Development, Jubilant Innovation, Bangalore, India (10% time), 2007

Jubilant Corporation, a major research services provider, initiated an internal startup to focus on drug development of NCEs in India. Recruit staff, provide strategic direction towards operations, evaluation of in-licensed compounds, sr. technical representative with potential corporate partners in the US.

Consultant to biotechnology companies and to CROs: work on a variety of projects, NDA stage and pre-IND projects, and strategic drug development issues

Sr. Vice President, Drug Development, DOV Pharmaceutical, Somerset, NJ, 2003-2006

Responsible for a staff of 60 in the departments of Pharmaceutical Development, Regulatory, Clinical Research, Data Management, Biostatistics and Medical Writing. Lead the bicifadine project team in the development of this novel analgesic for chronic lower back pain and for acute pain. Other programs being developed are triple re-uptake inhibitors for depression (phase II clinical trials) and substance abuse (phase I). A member of the senior management team of the Company and have close involvement with corporate deals, patent strategy, investor relations and Wall Street presentations.

Sr. Vice President, Scientific and Medical Services, PAREXEL International, Waltham, MA, 1999-2003

Responsible for the worldwide technical and business operations of the departments of Biostatistics and Programming, Medical, Medical Writing of PAREXEL International. This unit has approx. 280 employees and strong financial performance. Serve as internal consultant for large Programs and for general corporate strategy relative to new programs and technical expertise related services. Provide technical sales support.

Vice President, CNS Research PAREXEL International, Northbrook, IL, 1998-1999

Responsible for project and technical oversight of projects conducted on behalf of certain key clients in respect to clinical research services (clinical trials, monitoring, data bases, statistics, medical report writing, regulatory and technical support, etc.) and other PAREXEL activities. Serve as Executive Project Leader for large international clinical programs. Serve as internal technical consultant for issues and activities related to CNS drug development.

Executive Director of Clinical Research Forest Laboratories, Inc., New York, NY 1996-1998

Forest is a mid-sized pharmaceutical company focusing on CNS, respiratory and cardiovascular products. Responsibilities include supervision of the Medical and

Biostatistics Departments (staff of 50), extensive interactions with FDA and Marketing Department.

Senior Vice President of Research, Cato Research, Ltd. Durham, NC, 1990-1996

An independent consulting drug development research firm which deals largely with biotechnology and early stage development companies. Cato provides planning, implementation, and analysis of preclinical and clinical trials, and facilitates the FDA approval of new drug entities. Responsibilities included overall leadership of numerous concurrent projects in all therapeutic areas (including stroke, biological agents/cell therapeutics, pain, endocrinological disorders, CNS disorders, skin disorders, infectious disease, gi disorders and others. Also includes IND and NDA document creation and strategy, client relationships.

President, Research Triangle Pharmaceuticals Durham, NC 1991-1994

Research Triangle Pharmaceuticals was initially a subsidiary of Cato Holding Corporation. In 1994 it became an independent privately held company and was subsequently acquired in 2000 by SkyePharma. It specializes in the development of proprietary drug delivery systems and pharmaceutical technology for the improved treatment of disease.

President and Chief Executive Officer, Pharmatec, Inc. Alachua, FL, 1985-1989

Pharmatec, a publicly held R&D oriented company, specializes in drug delivery technology – a prodrug carrier system for delivering drugs to CNS and Molecusol brand cyclodextrin for solubilizing and stabilizing drugs. Responsibilities included all budgets, license negotiations, overall corporate strategy, investor relations and supervision of the senior scientists (mostly medicinal chemists) and marketing staff.

Director, New Products Department Marketing Unit, Burroughs Wellcome Co., Research Triangle Park, NC, 1983-1985

As the most senior member of this department, staff of five, responsibilities included interaction with approximately 25 project teams researching the investigational drugs under development. Project team input concerned development of R&D strategies which would optimize the commercial success of the product. Provided initial market forecasts for investigational drug projects, conducted market research and evaluated external compounds for in licensing.

Head, Clinical Neuroscience, Medical Division, Burroughs Wellcome Co., Research Triangle Park, NC, 1982-1983, Section Head, Psychiatry Section, 1976-1982

Reporting to the Medical Director, this position was responsible for the clinical research activity (IND, NDA, post NDA) of three sections having a total staff of about 30 – the psychiatry, neurology and anesthesia/analgesia groups. These sections developed clinical strategies for Phase I-III testing of new chemical

entities (9 INDs, 2 NDAs), study design, investigator selection, study monitoring and medical report writing. Also, was project leader for 8 years from early Phase II to NDA submission of bupropion (antidepressant).

- Adjunct Associate Professor, Department of Pharmacology
  University of Florida School of Medicine, Gainesville, FL, 1986-1989

- Member of the Scientific Board, Center for Drug Design and Delivery
  University of Florida, Gainesville, FL, 1986-1989

- Research Investigator, Neuropharmacology, Lab, Dorothea Dix Hospital, Raleigh, NC, 1972-1982

- Senior Research Investigator, Neuropharmacology Laboratory
  The Squibb Institute for Medical Research, Princeton, NJ, 1975-1976

- Postdoctoral Research Fellow, Research Associate, Staff Scientist; Neurophysiology Lab
  Worcester Foundation for Experimental Biology Shrewsbury, MA, 1970-1975

- Postdoctoral Research Fellow, Psychophysiology Laboratory, Boston State Hospital
  Boston, MA, 1969-1970

LICENSURE AND CERTIFICATION

U.S. PATENTS:

4,347,257 (suppression of prolactin secretion by bupropion)
4,438,138 (reduction of cholesterol by bupropion)
4,435,449 (treatment of minimal brain dysfunction by bupropion)
4,786,647 (method for eliciting anxiolysis)

U.S. PATENTS PENDING:

- Method and compositions for reducing injection site toxicity.
- Method and compositions for solubilization and stabilization of polypeptides, especially proteins.
- Use of bicifadine in antipyresis
    - Use of bicifadine sustained release formulations
    - Inhibition of gastric acid secretion as a method for treatment of snoring and other sleep related breathing disorders.

HONORS

First Prize for paper presented at the Psychopharmacology, Division of American Psychology Association, 1971
Research Fellowship, Worcester Foundation for Experimental Biology, 1970
Research Fellowship, Boston State Hosp., 1969
Graduate School Assistantship, Indiana University, 1965-1969
New York State Regents Scholarship, 1961-1965

PUBLICATIONS

PUBLICATIONS AND PRESENTATIONS:

1. Beer B, Ieni JR, Wu W, Clody D, Aurorusi P, Rose J, et al. A placebo-controlled safety, pharmacokinetic and psychometric evaluation in normal volunteers of single, escalating doses of CL 284,846, a non-benzodiazepine hypnotic. J Clin Pharmcol 1994; 34:335-344.

2. Olsen EA, Cato AE, Allan G, Meyer C, Hopkins S, Clive CM, et al. A pilot study of the safety and pharmacokinetics of 1% methotrexate/3% Azone in patients with psoriasis vulgaris. Arch Dermatol 1993.

3. Stern WC. Delivery systems for reducing drug toxicity: Redox carriers for penetrating the blood-brain barrier and Molecusol brand cyclodextrin for drug solubilization. In: Salem H, Baskin SI, editors. New technologies and concepts for reducing drug toxicities. Boca Raton: CRC Press, 1993:87-97.

4. Von Eschen K, Ulrich J, Howell S, Cato AE, Vargas R, Stern WC. Safety and immunostimulatory activity of monophosphoryl lipid A (MLA) for normal human volunteers. Int Congress for Antimicrobial Agents and Chemotherapy 1992;

5. Stern WC. Cyclodextrin-based drug delivery. Pharm News Perspectives 1989.

6. Anderson WR, Simpkins JW, Woodard PA, Stern WC, Bodor NS. Anxiolytic activity of a brain delivery system for GABA. Psychopharmacol 1987; 92:157-163.

7. Crenshaw TL, Goldberg J, Stern WC. Pharmacologic modification of psychosexual dysfunction. J Sex Marital Ther 1987; 13:239-252.

8. Feighner J, Hendrickson G, Miller L, Stern WC. Double-blind comparison of doxepin versus bupropion outpatients with a major depressive disorder. J Clin Psychopharmacol 1986; 6(1):27-32.

9. Stern WC, Pugh WW, Morgane PJ. Single unit activity in frontal cortex and caudate nucleus of young and old rats. Neurobiol Aging 1985; 6(3):245-248.

10. Wright G, Galloway RM, Kim J, Dalton M, Miller L, Stern WC. Bupropion in a long-term treatment of cyclic mood disorders. Mood stabilizing effects. J Clin Psychiatry 1985; 46:22-25.

11. Berken GH, Weinstein DO, Stern WC. Weight gain: a side effect of tricyclic antidepressants. J Affect Disord 1984; 7(2):133-138.

12. Feighner JP, Meredith CH, Stern WC. Double-blind study of bupropion and placebo in depression. Am J Psychiatry 1984; 141:525-532.

13. Kirksey D, Stern WC. Private practice evaluation of the study and efficacy of bupropion in depressed geriatric outpatients. Curr Ther Res 1984; 35(2):200-210.

14. Pugh WW, Stern WC. Horseradish peroxidase labeling of extracellular single unit recording sites. Brian Res 1984; 12:419-423.

15. Stern WC, Pugh WW, Resnick O, Morgane P. Developmental protein malnutrition in the rat: effects on single-unit activity in the frontal cortex. Brain Res 1984; 304:227-234.

16. Farid F, Wenger T, Tsai S, Singh B, Stern WC. Use of bupropion in patients who exhibit orthostatic hypotension on tricyclic antidepressants. J Clin Psychiatry 1983; 44:170-173.

17. Halaris A, Stern WC, Van Wyck Fleet J. Evaluation of the safety and efficacy of bupropion in depression. J Clin Psychiatry 1983; 44:101-103.

18. Harto-Truax N, Stern WC, Miller L. The effects of bupropion on body weight. J Clin Psychiatry 1983; 44:183-186.

19. Miller L, Stern WC. Bupropion: an empirical pharmacological approach to drug development. In: Usdin E, editor. Frontiers in neuropsychiatric research. London: MacMillan Press, Ltd. 1983:195-224.

20. Othmer E, Othmer S, Stern WC, Van Wyck Fleet J. Long-term efficacy and safety of bupropion. J Clin Psychiatry 1983; 44:153-156.

21. Peck A, Stern WC, Watkinson C. The incidence of seizures during treatment with tricyclic antidepressant drugs and bupropion. J Clin Psychiatry 1983; 44:197-201.

22. Shopsin B, Soper R, Tyrer S, Van Wyck Fleet J, Stern WC. Bupropion (Wellbutrin) - imipramine study: a single-blind comparison in depressed outpatients. Curr Ther Res 1983; 33:339-361.

23. Stern WC, Pugh WW, Johnson A, Morgane PJ. Spontaneous forebrain neuronal activity in developmentally protein malnourished rats. Dev.Brain Res. 1983; 9:95-98.

24. Stern WC, Harto-Truax N, Bauer N. Efficacy of bupropion in tricyclic-resistant or intolerant patients. J Clin Psychiatry 1983; 44:148-152.

25. Van Wyck Fleet J, Manberg P, Miller L, Harto-Truax N, Sato T, Fleck R, et al. Overview of clinically significant adverse reactions to bupropion. 1983; 44:191-196.

26. Wenger T, Stern WC. The cardiovascular profile of Wellbutrin. J Clin Psychiatry 1983; 44:176-182.

27. Harto-Truax N, Van Wyck Fleet J, Stern WC. Double-blind comparison of bupropion vs. amitriptyline in depressed out-patients. Psychopharmacol Bull 1982; 17:72-76.

28. Stern WC, Harto-Truax N, Rogers J, Miller L. Clinical profile of the novel antidepressant bupropion. In: Costa E, Racagni G, editors. Typical and atypical antidepressants, clinical practice, advances in biochemical psychopharmacology. New York: Raven Press, 1982:21-34.

29. Maxwell RA, Mehta NB, Tucker WE, Schroeder DH, Stern WC. Bupropion. In: Goldberg ME, editor. Pharmacological and biochemical properties of drug substances. Washington (DC): American Pharmaceutical Association Academy of Pharmaceutical Sciences, 1981:1-55.

30. Stern WC, Johnson A, Bronzino JD, Morgane PJ. Neuropharmacology of the afferent projections from the lateral habenula and substantia nigra to the anterior raphe in the rat. Neuropharmacol 1981; 20:979-990.

31. Stern WC, Harto-Truax N. Two multicenter studies of the antidepressant effects of Wellbutrin (bupropion HCl) versus placebo. Psychopharmacol Bull 1980; 16:43-46.

32. Stern WC, Johnson A, Morgane P, Bronzino JD. Influence of electrical stimulation of the region of the area postrema nucleus of the solitary tract on unit activity in the anterior raphe and the cortical electroencephalogram of the rat. Exp.Neurol. 1980; 67:391-398.

33. Morgane PJ, Resnick O, Stern WC, Forbes WB, Miller R, Leahy JP, et al. Maternal protein malnutrition and the developing nervous system. In: Levitsky D, editor. Malnutrition, environment and behavior: new perspectives. Ithaca (NY): Cornell University Press, 1979:94-122.

34. Stern WC, Johnson A, Bronzino JD, Morgane PJ. Influence of bupropion HCl (Wellbutrin), a novel antidepressant, on plasma levels of prolactin and growth hormone in man and rat. Life Sci. 1979; 25:1717-1724.

35. Stern WC. Sleep and anxiolytics. In: Fielding S, Lal H, editors. Industrial pharmacology. Mt. Kisco (NY): Future Publishing, 1979:117-139.

36. Stern WC, Johnson A, Bronzino JD, Morgane PJ. Effects of electrical stimulation of the lateral habenula on single-unit activity of raphe neurons. Exp.Neurol. 1979; 65:326-342.

37. Stern WC, Johnson A, Bronzino JD, Morgane PJ. Influence of electrical stimulation of the substantia nigra on spontaneous activity of raphe neurons in the anesthetized rat. Brain Res Bull 1979; 4:561-565.

38. Forbes W, Stern WC, Tracy CA, Resnick O, Morgane PJ. Effect of chronic protein malnutrition on experimentally induced seizures in the rat. Exp.Neurol. 1978; 62:475-481.

39. Leahy JP, Stern WC, Resnick O, Morgane PJ. A neuropharmacological analysis of central nervous system catecholamine systems in developmental protein malnutrition. Dev.Psychobiol. 1978. 11:361-370.

40. Morgane PJ, Miller M, Kemper T, Stern WC, Forbes W, Hall R, et al. The effects of protein malnutrition on the developing central nervous system in the rat. Neurosci Behav Rev 1978; 2:137-230.

41. Morgane PJ, Stern WC. Serotonin in the regulation of sleep. In: Essman W, editor. Serotonin and health disease. Vol. II. Physiological regulation and pharmacological action. New York: Spectrum Publications, 1978:205-245.

42. Jacobs B, Trulson M, Stern WC. Behavioral effects of LSD in the cat: proposal of an animal model for studying the actions of hallucinogens. Brain Res 1977; 132:301-314.

43. Miller M, Leahy JP, Stern WC, Morgane PJ, Resnick O. Tryptophan availability: relation to elevated brain serotonin in developmentally protein-malnourished rats. Exp.Neurol. 1977; 57:142-157.

44. Morgane PJ, Stern WC, Bronzino JD. Experimental studies of sleep in animals. In: Myers RD, editor. Methods in psychobiology. New York: Academic Press, 1977:189-240.

45. Stern WC, Morgane PJ. Growth hormone: effects on sleep and brain neurochemistry. In: Drucker-Colin R, McGaugh J, editors. Neurobiology of sleep and memory. New York: Academic Press, 1977:373-400.

46. Bronzino JD, Stern WC, Leahy JP, Morgane PJ. Sleep cycles in cats during chronic electrical stimulation of the area postrema and the anterior raphe. Brain Res Bull 1976; 1:235-239.

47. Bronzino JD, Stern WC, Leahy JP, Morgane PJ. Power spectral analysis of EEG activity obtained from cortical and subcortical sites during the vigilance states of the cat. Brain Res Bull 1976.

48. Jacob BJ, Trulson M, Stern WC. An animal model of LSD action. Science 1976; 194:741-743.

49. Stern WC, Miller M, Forbes WB, Leahy JP, Morgane PJ, Resnick O. Effects of protein malnutrition during development on protein synthesis in brain and peripheral tissues. Brain Res Bull 1976; 1:27-31.

50. Stern WC, Resnick O, Morgane PJ. Developmental protein malnutrition in rats. Acquisition and long-term retention of a single alternation discrimination. Nutr Rep International 1976; 14:475-483.

51. Forbes WB, Stern WC, Bronzino JD, Resnick O, Morgane PJ. The effect of chronic protein malnutrition on non-specific thalamocortical evoked potentials in the rat. Physiol.Behav. 1975; 14:655-658.

52. Forbes WB, Resnick O, Stern WC, Bronzino JD, Morgane PJ. The effect of chronic protein malnutrition on trans-callosal evoked responses in the rat. Dev.Psychobiol. 1975; 8:503-509.

53. Stern WC, Jalowiec JE, Morgane PJ, Shabshelowitz H. Effects of growth hormone in sleep-waking patterns in cats. Horm.Behav. 1975; 6:189-196.

54. Stern WC, Miller M, Forbes WB, Morgane PJ, Resnick O. Ontology of the levels of biogenic amines in regional brain areas and peripheral tissues in normal and protein malnourished rats. Exp.Neurol. 1975; 49:314-326.

55. Stern WC, Miller M, Jalowiec JE, Forbes WB, Morgane PJ. Effects of growth hormone on brain biogenic amine levels. Pharmacol Biochem Behav 1975; 3:1115-1118.

56. Stern WC, Miller M, Resnick O, Morgane PJ. Distribution of ^{125}I-labelled rat growth hormone in regional brain areas and peripheral tissues of the rat. Am J Anat 1975; 144:502-507.

57. Stern WC, Miller M, Morgane PJ, Resnick O. Protein malnutrition in rats: response of brain amines and behavior to foot shock stress. Exp.Neurol. 1975; 47:56-67.

58. Bronzino JD, Morgane PJ, Forbes WB, Stern WC, Resnick O. Ontogeny of visual evoked responses in protein malnourised rats during development. Biol.Psychiatry 1974; 14:175-184.

59. Morgane PJ, Stern WC. Rhythms of the biogenic amines in the brain and sleep. In: Scheving LW, Halberg F, Pauly JE, editors. Chronobiology. Tokyo: Igaku Shoin, 1974:506-511.

60. Morgane PJ, Stern WC. Interaction of amine systems in the central nervous system in the regulation of the states of vigilance. In: Myers RD, Drucker-Colin RR, editors. Neurohumoral coding of brain function. New York: Plenum Press, 1974:289-309.

61. Morgane PJ, Stern WC. Chemical anatomy of brain circuits in relation to sleep and wakefulness. In: Weitzman E, editor. Advances in sleep research. New York: Spectrum Publications, 1974:1-131.

62. Stern WC, Forbes WB, Morgane PJ. Absence of PGO spikes in rats. Physiol.Behav. 1974; 12:293-295.

63. Stern WC, Morgane PJ. REM sleep function: maintenance of catecholamine systems in the central nervous system. Behav.Biol. 1974; 11:1-32.

64. Stern WC, Forbes WB, Resnick O, Morgane PJ. Seizure susceptibility and brain amine levels following protein malnutrition during development in the rat. Brain Res 1974; 79:375-384.

65. Bronzino JD, Brusseau JN, Stern WC, Morgane PJ. Power density spectra of cortical EEG of the cat in sleep and waking. Electroencephalogr.Clin.Neurophysiol. 1973; 35:187-191.

66. Jalowiec JE, Panksepp J, Shabshelowitx H, Zolovick AJ, Stern WC, Morgane PJ. Suppression of feeding in cats following 2-deoxy-d-glucose. Physiol.Behav. 1973; 10:805-807.

67. Jalowiec JE, Morgane PJ, Stern WC, Zolovick A, Panksepp J. Effects of midbrain tegmental lesions on sleep and regional brain serotonin and norepinephrine levels in cats. Exp.Neurol. 1973; 41:670-682.

68. Morgane PJ, Stern WC. Monoaminergic systems in the brain and their role in the sleep states. In: Usdin E, Barchas J, editors. Serotonin and behavior. New York: Academic Press, 1973:427-442.

69. Morgane PJ, Stern WC. Effects of serotonin metabolites on sleep-waking activity in cats. Brain Res 1973; 50:205-213.

70. Panksepp J, Zolovick A, Jalowiec J, Stern WC, Morgane PJ. Fenfluramine: effect on aggression. Biol.Psychiatry 1973; 6:181-186.

71. Panksepp J, Jalowiec JE, Morgane PJ, Zolovick A, Stern WC. Noradrenergic pathways and sleep-waking states in cats. Exp.Neurol. 1973; 41:233-245.

72. Panksepp JE, Morgane PJ, Stern WC, Zolovick AJ, Jalowiec J. Inhibition of glycologic metabolism and sleep-waking states in cats. Pharmacol Biochem Behav 1973; 1:117-119.

73. Stern WC, Morgane PJ. Effects of reserpine on sleep and brain biogenic amine levels in the cat. Psychopharmacologia 1973; 28:275-286.

74. Stern WC, Morgane PJ. Effects of α-methyl-tyrosine in REM sleep and brian amine levels in the cat. Biol.Psychiatry 1973; 6:301-306.

75. Zolovick AH, Stern WC, Jalowiec JE, Panksepp J, Morgane PJ. Sleep-waking patterns and brain biogenic amine levels in cats after administration of 6-hydroxydopamine into the dorso-lateral pontine tegmentum. Pharmacol Biochem Behav 1973; 1:557-567.

76. Zolovick AJ, Panksepp J, Jalowiec JE, Stern WC, Morgane PJ. Sleep-waking patterns in cats after administration of fenfluramine and other monoaminergic modulating drugs. Pharmacol Biochem Behav 1973; 1:41-46.

77. Bronzino JD, Morgane PJ, Stern WC, Bottaro S. A new design for an exploring chemode. Electroencephalogr.Clin.Neurophysiol. 1972; 32:195-198.

78. Bronzino JD, Morgane PJ, Stern WC. EEG synchronization following application of serotonin to area postrema. Am J Physiol 1972; 223:376-383.

79. Bronzino JD, Brusseau J, Morgane PJ, Stern WC. Power spectrum analysis of EEG synchronization following application os serotonin to area postrema. Ann.Biomed.Eng. 1972; 1:246-253.

80. Bronzino JD, Brusseau J, Morgane PJ, Stern WC. Analysis of EEG synchronization using power spectrum techniques. Proceedings of the 1972 International Conference on Cybernetics and Society 1972;67-71.

81. Hartmann E, Stern WC. Desynchronized sleep deprivation: learning deficit and its reversal by increased catecholamines. Physiol.Behav. 1972; 8:585-587.

82. Morgane PJ, Bronzino JD, Stern WC. An exploration chemitrode device for direct chemical stimulation of the brain. J.Appl.Physiol. 1972; 32:138-142.

83. Morgane PJ, Stern WC. Relationship of sleep to neuroanatomical circuits, biochemistry and behavior. In: Haydu G, editor. Patterns of integration from biochemical to behavioral processes. Annals of the New York Academy of Sciences, 1972:95-111.

84. Stern WC, Hartmann E. Reduced amphetamine lethality following chronic stress. Pharmacopharmacologia 1972; 23:167-170.

85. Stern WC, Hartmann E, Draskoczy PR, Schildkraut JJ. Behavioral effects of centrally administered 6-hydroxydopamine. Psychol.Rep. 1972; 30:815-820.

86. Stern WC, Morgane PJ, Bronzino JD. LSD: effects on sleep patterns and spiking activity in the lateral geniculate nucleus. Brain Res 1972; 41:199-204.

87. Stern WC, Morgane PJ. Serotonin and EEG spiking acitivity in the LGN. Proceedings of the 80th Annual Convention of the American Psychological Association 1972;837-838.

88. Stern WC, Morgane PJ, Panksepp J, Zolovick A, Jalowiec J. Evaluation of REM sleep following inhibition of protein synthesis. Brain Res 1972; 47:254-258.

89. Stern WC, Miller FP, Cox RH, Maickel RP. Brain norepinephrine and serotonin levels following REM sleep deprivation in the rat. Psychopharmacologia 1971; 22:50-55.

90. Stern WC, Hartmann E. Catecholamines and desynchronized sleep. Proc Am Psychol Assoc 1971;743-744.

91. Stern WC. Effects of desynchronized sleep deprivation on startle response habituation in rats. Psychonomic Sci. 1971; 23A:31-32.

92. Stern WC. Acquisition impairments following rapid eye movement sleep deprivation in rats. Physiol.Behav. 1971; 7:345-352.

93. Stern WC. REM sleep and learning: animal studies. In: Hartmann E, editor. Sleep and dreaming. Boston: Little, Brown and Co. 1970:249-257.

94. Stern WC, Heise GA. Failure to enhance alteration discrimination learning in rats. Physiol.Behav. 1970; 5:449-452.

95. Segal DS, Cox RH, Stern WC, Maickel RP. Stimulatory effect of pemoline and cyclopropylpemoline on continuous avoidance behavior: similarity to effects of d-amphetamine. Life Sci. 1967; 6:2567-2572.

96. Myers B, Stern WC. Effect of bilateral spreading depression and scopolamine on motor activity in rats. Psychol.Rep. 1966; 18:267-270.

date redacted

Exhibit A

AGREEMENT
Between
WARREN STERN
And
SOHNSTEARNS, LLC

date redacted

1. Warren Stern ("WS") and SohnStearns LLC ("SS") hereby enter into this Agreement with the intent of developing intellectual property, obtaining patents, and commercializing a pharmaceutical for the treatment of snoring, sleep apnea and related disorders.

2. WS and SS hereby form Newco for the purpose of accomplishing the intent of this Agreement. NCO shall be either incorporated or formed into a partnership within thirty days of this Agreement.

3. WS and SS shall each own 50% of Newco and its successor corporation or partnership. WS and SS shall have equal representation on Newco's board of directors and on any other governing or policy-making committee related to Newco. Neither WS nor SS shall sell or transfer of any if its ownership of Newco, other than to family members of WS or to family members of the principals of SS, without first giving the other party (WS or SS) the right of first refusal to acquire that ownership in Newco on the same terms as the intended sale or transfer.

4. WS shall provide Newco with intellectual property related to snoring.

5. If patents are granted on this intellectual property, the patents shall be held in the name of WS. WS agrees to assign any and all of these patents at no charge and for the life of these patents to Newco and its successors.

6. If Newco fails to establish certain objectives, to be stipulated in an addendum to this Agreement, the assignment of any and all of theses patents shall be voided and all rights of the patents shall revert exclusively to WS.

7. WS shall contribute to Newco a protocol for performing clinical trials for the snoring related pharmaceutical and shall also contribute additional information necessary for Newco to obtain patents on this pharmaceutical.

8. SS shall contribute the performance of the management function for Newco.

date redacted

9. SS shall contribute or obtain all funding necessary for capitalizing Newco and its snoring related clinical trials. If WS and SS agree that funds should be raised from third parties, then WS and SS shall equally bear any dilution resultant from obtaining these funds. The terms of any third party investment in Newco, including the identity of the investors, the amount of investment, and the amount of Newco awarded to the investors, shall require the approval of both WS and SS.

10. All profits from Newco's business shall be split 50% to WS and 50% to SS. Profits are defined as all of Newco's revenues, less all of Newco's operating expenses, and after the payback of all investor funds.

11. WS and SS shall treat all information related to Newco as confidential, as defined in the Confidentiality Agreement between WS and SS dated April 5, 2002.

12. This Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

date redacted

Warren Stern Date

For SohnStearns LLC:

Stephen Sohn Date

Robert Stearns Date

Exhibit B

CONFIDENTIALITY AGREEMENT

This Agreement made on date redacted between

Doug Bell, M.D.

And

Steve Sohn, MD

Steve Sohn, MD ("Sohn") shall disclose to Doug Bell, M.D. ("Bell") information related to an invention concerning a new pharmacological treatment of snoring, insomnia and related sleep disorders. Bell agrees to not disclose this information to any third party without the prior written consent of Sohn, except to the extent that such persons receiving the information shall be bound and obligated by the same provisions of confidentiality as provided herein. This confidentiality requirement shall be waived in the context of the filing of a patent application(s).

The foregoing obligation shall not apply to information:

a) Which was known to the Bell prior to receipt from Sohn;

b) Which is or lawfully becomes generally available to the public;

c) Which is lawfully acquired from third parties who have a right to disclose such information;

d) Which by mutually written agreement is released from a confidential status; and

e) Which Bell is required by law to release, provided Bell provides prompt written notice to Sohn of such request to enable Sohn to obtain an appropriate protective order .

2. Neither this Agreement nor the disclosure by Sohn of Confidential Information to Bell shall be deemed by implication or otherwise to vest in Bell any rights, licenses or patents in or to the Confidential Information.

3. Bell's obligations hereunder shall survive the termination of its business relationship with Sohn and shall remain in effect for 7 years from the date of this agreement.

This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts.

Sincerely,

S. Sohn, M.D.

189 Islington Road
Newton, MA 02466

Date: date redacted

Agreed to and accepted by;

D. Bell, M.D.

Douglas Bell, MD

One Brookline Place
Brookline, MA 02445

Date: date redacted

Exhibit C

Stern, Warren

Subject: DATA EXTRACTION FORM FOR STUDY CONDUCTED BY D. BELL, MD

DEMOGRAPHY

PATIENT INITIALS R.G. AGE(YRS) DOB - 06-26-52

SEX M WEIGHT (lbs) 175 lbs RACE W

DIAGNOSES: SLEEP DISORDERS SNORING, SLEEP APNEA

GASTROINTESTINAL

OTHER NASAL CONGESTION

STUDY PERIOD date redacted

START OF STUDY [redacted] END OF STUDY date redacted

TREATMENTS (DATES) RECEIVED DURING THE STUDY FLONASE + ATENOLOL - 30mg.

INTER-CURRENT ILLNESSES DURING THE STUDY PERIOD NONE

ADVERSE EVENTS (EVENT, DATE, SEVERITY) NONE

SLEEP/SNORING MEASURES

BASELINE VALUES:
-SLEEP RECORD ALL REPORT - MODERATE SLEEP APNEA.

-GLOBAL ASSESSMENT BY DR. BELL NASAL OBSTRUCTION
LOW PALATE.

-PATIENT SPOUSE RATINGS

MODERATE SNORING

VALUES AT THE END OF TREATMENT:

-SLEEP RECORD

PT. HAD SURGERY LATER

-GLOBAL ASSESSMENT BY DR. BELL

25% IMPROVEMENT - PREVIO -

-PATIENT SPOUSE RATINGS

25% IMPROVEMENT — MEDS ONLY

OTHER OBSERVATIONS:

PT. LATER HAD NASAL + PALATE SURGERY -
APNEA RESOLVED
MIN. SNORING-